REMARKS

After entry of the present Amendment, claims 1-9, 11-13, 15, 17, 18, 23-32, 48, 49 and 54 are pending in the Application. Claims 19-22, 33-47 and 50-53, drawn to a non-elected invention, have been cancelled in order to place the application in condition for allowance. Claims 1 and 49 were amended for purposes of clarity. The further features of claim 1 are supported in the specification at least at page 3, paragraph 11. The recitation of a sperm cell in claim 1 is made to particularly claim an embodiment of the invention, however, applicants reserve the right to file a continuing application directed to further reproductive cells. Claim 54 is newly presented, but does not introduce new matter. In particular, support for claim 54 is found at least at page 3, paragraph 11.

The pending claims stand variously rejected. Each rejection is respectfully traversed as discussed below. Applicants respectfully submit that the presently pending claims are in condition for allowance and earnestly solicit early notification to that effect.

Telephonic interview of the Examiner

Applicants appreciate the time and courtesy extended by the Examiner in a telephonic interview with Applicants' undersigned representative and inventor Rozeboom on June 10, 2004. In the interview, the Examiner suggested several clarifying amendments to claim 1 that may be considered favorably in distinguishing the cited references regarding seminal fluid. The Examiner also indicated that a Declaration would be considered if submitted with the present Response. The cited references were briefly discussed. Applicants' arguments are included below.

The claimed invention

The Office Action characterizes the claimed invention as having three major components: 1) a reproductive cell and a medium; 2) IGF; and 3) TGF. Office Action at page 2. In fact, a proper interpretation of claim 1 (and the remaining claims in the application, which depend directly or indirectly therefrom) requires the following components:

1) a sperm cell; and
2) a medium comprising:
    a) IGF; and
    b) TGF;

3) where the medium is a collection, holding, processing, in vitro fertilization, sexing, culturing or storage medium.

In other words, by combining the sperm cell and the medium into a single component, the Office Action fails to recognize that the medium is a positively recited element of the claimed invention, separate from the sperm cell and that the claimed medium comprises both IGF and TGF.

The distinction is important. When claim 1 is properly construed in light of the specification, it is evident that the IGF and TGF are exogenous, i.e., are added to the media as components of the media formulation. This is especially clear in the context of the specification. For example, page 4, paragraph 15 states that the growth factors "may be obtained from any commercially available source," and page 5, paragraph 20 discusses how to determine optimal concentrations of growth factors "by preparing a series of media with differing concentrations of growth factor..." Similarly, at page 6, paragraph 26 to page 7, paragraph 28, the specification discusses means of preparing the media compositions and adjusting concentrations of growth factor as desired by the practitioner.

Applicants recognize that claims are given the broadest reasonable construction for the purposes of examination. MPEP 2111. However, the broadest reasonable construction must also be consistent with the Applicant's disclosure and the interpretation that those skilled in the art would reach. MPEP 2111, citing *In re Morris*, 127 F.3d 1048 (Fed. Cir. 1997). Applicants respectfully assert that in this case, the Examiner's construction of the claims is not reasonable, as it is not consistent with either applicants' disclosure or the interpretation that would be applied to the claims by those of skill in the art. See Rozeboom Declaration, paragraph 6. In particular, Applicants respectfully assert that the Examiner has failed to properly construe the claim term "medium."

The Office Action makes clear that the Examiner has erroneously interpreted "medium" to include seminal fluid. See, e.g., page 3, line 3: "seminal plasma (medium)." In contrast to the Examiner's construction, Applicant's specification defines "sperm cell medium" as "any medium used for the collection, holding, processing, in vitro fertilization, sexing, culturing, or storing (including long-term cryopreservation) of mammalian, avian, or piscian sperm cells, and includes both solid and liquid compositions, as well as solid compositions that are reconsistituted or mixed with a liquid carrier, such as water, for use."

Page 3, paragraph 11. This definition clearly excludes seminal plasma, which would not be appropriate for any of the claimed media functions. See Rozeboom Declaration, paragraphs 7 and 9. Moreover, the specification clearly distinguishes semen (seminal fluid) from media in several contexts. For example:

> Boar *semen* is generally diluted or extended with a suitable storage *medium*...the culture *medium* serves to increase the total volume of the sample. Page 1, paragraph 4 (emphasis added).

> Many specific *media* formulations are known or are available commercially, including...extenders for preserving *semen*. Page 3, paragraph 12 (emphasis added).

Thus, the context of the application makes clear that storing and maintaining sperm beyond its normal viability for a number of purposes are functions of cell media not served by seminal fluid alone. Moreover, throughout the specification, the terms "semen" and "media" are not used interchangeably, as they would be if they were meant to be mutually inclusive terms.

As clearly evidenced by the enclosed Declaration of Dr. Kevin Rozeboom, one of skill in the art would also not consider seminal plamsa or ejaculate to be a "sperm cell medium." The terms are not understood to be synonymous, nor is seminal fluid considered sperm cell media. Rozeboom Declaration at paragraph 6.

Applicants respectfully assert that, when "sperm cell medium" is properly characterized, the prior art rejections are obviated, as discussed in further detail below.

Rejections under 35 U.S.C. § 102(b)

Claims 1, 2, 7, 11-13, 15, 17, 32 and 49 stand rejected as anticipated under 35 U.S.C. § 102(b) by Naz et al. in light of evidence provided in Lackey et al. and Nocera et al. Claims 1, 2, 7, 11-13, 15, 17, 29, 32, 48 and 49 stand rejected as anticipated under 35 U.S.C. § 102(b) by Ovesen et al. in light of evidence provided in Nocera et al. and U.S. Patent No. 4,156,427.

These rejections are respectfully traversed.

In order to anticipate, a reference must teach every aspect of the invention either explicitly or impliedly. MPEP 2131. Applicants respectfully assert that neither Naz et al. nor Ovesen et al. explicitly or impliedly disclose every aspect of the claimed invention as required by this standard.

Naz et al.

The Office Action states that Naz et al. discloses sperm samples taken from donors and that the collected samples contain "sperm cells (component 1) and seminal plasma (medium) containing IGF (component 2) and TGF (component 3)."

Applicants respectfully assert that at least for the reasons discussed above and in the Rozeboom Declaration, Naz et al. fails to disclose a medium comprising the recited components, as required by the claims. As stated above, seminal fluid is not a "medium" as defined by the instant application and incorporated into the claims. Thus, the Examiner's conclusion that "the collected semen samples or semen ejaculates are compositions identical to the instant claims 1,2, 7, 11-13, 15 and 17" is incorrect. With respect to dependent claims 29, 32, 48 and 49, each requires the limitations of claim 1, i.e., a medium, in addition to further limitations, and therefore are also not anticipated by Naz et al. New claim 54, in addition to requiring the limitations of claim 1, require that the media be in a solid form, which clearly is not encompassed by the seminal fluid of Naz et al. and is therefore also allowable over the cited reference.

Lackey et al. and Nocera et. al., cited by the Examiner as evidence of additional components of seminal fluid, do not cure the deficiency of Naz et al., namely, that it does not teach a medium comprising at least one insulin-like growth factor and at least one transforming growth factor.

Because the cited reference fails to anticipate the rejected claims by teaching every aspect of the claimed invention, Applicants respectfully request withdrawal of the rejection and notification to that effect.

Ovesen et al.

The Office Action states that Ovesen et al. "discloses collected semen samples or ejaculates that contain human sperm cells and human seminal plasma," and concludes that the

seminal samples are identical to the composition of claims 1, 2, 7, 11-13, 15, 17, 29, 32 and 48 and 49.

Applicants respectfully assert that at least for the reasons discussed above and in the Rozeboom Declaration, Ovesen et al. fails to disclose a sperm cell medium including the recited components, as required by the claims. Simply, seminal fluid is not a "medium" as that term is defined in the present application. Since seminal fluid is not a medium, that it may inherently contain TGF and IGF is of no moment. Thus, the Examiner's conclusion that Ovesen's disclosure of the composition of human seminal fluid anticipates the claimed invention is incorrect, even in light of evidence in Nocera et al. and U.S. Patent No. 4,156,427 regarding further components of seminal fluid. New claim 54, in addition to requiring the limitations of claim 1, requires that the media be in solid form, which is clearly not encompassed by the human seminal samples of Ovesen et al. and is therefore also allowable over the cited reference.

Because the cited reference fails to anticipate the rejected claims by teaching every aspect of the invention, Applicants respectfully request withdrawal of the rejection and notification to that effect.

Rejection under 35 U.S.C. §102/103

Claims 1-9, 11-13, 15, 17, 18, 29, 32, 48 and 49 stand rejected as anticipated under 35 U.S.C. § 102(b) by Ovesen et al. in light of evidence provided in Nocera et al. and U.S. Patent No. 4,156,427, or in the alternative, under 35 U.S.C. § 103 as obvious over Ovesen et al. in view of Nocera et al., U.S. Patent No. 4,156,427, Gerfen et al. and Vardinon et al.

The rejection is respectfully traversed.

For the reasons discussed above, none of the rejected claims are anticipated by Ovesen et al. in light of evidence provided in Nocera et al. and U.S. Patent No. 4,156,427. Moreover, because Ovesen et al. does not teach a composition comprising a media, as properly construed, and because none of the secondary references cure this deficiency, none of the rejected claims are obvious, either.

The Office Action states again that "Ovesen et al. discloses a composition that is identical to the presently claimed composition since it contains animal or human sperm cells,

and animal or human seminal plasma..." Office Action at page 5. For the reasons discussed above, the interpretation of cell medium which reads the term to encompass seminal plasma is improper.

The Office Action cites the secondary references for their teachings regarding further animal species and animal seminal plasma concentrations of growth factors, transferrin, inositol, fructose, cryopreservative and zinc. However, none of the cited references teach that these claimed components may be added to a reproductive cell medium, as required by the instant claims as properly interpreted.

For these reasons, it is respectfully asserted that the rejected claims are neither anticipated by nor obvious over the cited references and withdrawal of the rejection is earnestly solicited.

Rejection under 35 U.S.C. § 103

Claims 1-9, 11-13, 15, 17, 18, 23-32, 48 and 49 stand rejected obvious over Naz et al. and Lackey et al. in view of the ATCC catalogue, U.S. Patent No. 6,140,121, U.S. Patent No. 6,150,163 and Nocera et al.

The rejection is respectfully traversed. This rejection, originally presented in the Office Action dated August 20, 2003 and repeated in the present Office Action, was originally traversed in the Amendment and Response filed November 20, 2003, incorporated herein by reference. The Office Action states that Applicants' prior arguments were not found to be persuasive. Applicants further respond as follows.

As discussed above, Naz et al. does not teach a medium comprising the claimed components. Moreover, Naz et. al. provides no motivation and no reasonable expectation of success that would lead one of skill in the art to incorporate TGF-β1 in a media composition, in combination with IGF.

Contrary to the Examiner's assertion that Naz et al. teaches "another benefit of the TGF such as enhanced expression of proteins that are regarded as important for proper sperm development and new protein synthesis," the reference actually teaches that the enhanced expression of the 50 kDa protein related to 2-5(A)synthetase has no effect on sperm function. Naz et al. teach:

> TGF-β1 enhances the expression of a 50 kDa protein in sperm cells that seems to be related to synthetase. The increase in synthetase-related protein expression does not apparently affect sperm function (motility and SPA). Page 162, Col. 2.

Naz et al. also teach:

> Our data indicate that sperm motility and capacitation of sperm cells were not affected by an increase of 50 kDa protein related to 2-5(A)synthetase. Page 162, Col. 1.

At most, Naz et al. teach that the 50 kDa protein and other minor proteins "may have a role in human sperm cell function." Page 162, Col. 2. Far from providing motivation to incorporate TGF in sperm cell media, this statement provides at most, an invitation for further experimentation -- experimentation that, in any event, would not involve media compositions at all. Moreover, this speculative statement is overcome by the definitive statements in Naz et al. that any enhanced protein synthesis provided by TGF does not affect sperm function.

Similarly, Lackey et al. does not teach a medium comprising the claimed components. Contrary to the Examiner's assertion, Applicants' prior Response acknowledges that Lackey et al. teach that IGFs in seminal plasma have an effect on sperm motility. However, Applicants respectfully assert that this teaching is insufficient to provide motivation to produce any media composition, much less the claimed compositions. Lackey provides no motivation or even suggestion to provide a composition comprising a sperm cell and a medium and further fails to teach or suggest combining IGF and TGF in such a medium.

Applicants maintain that the secondary references fail to cure these deficiencies for the reasons already of record.

The Examiner further states that the references are all in the same field of endeavor and seek to solve the same problem as the instant application "such as to provide a sperm culture medium." Office Action at page 11. Applicants strongly disagree with this characterization of the references. Naz et al., Lackey et al. and Nocera et al., far from teaching media compositions suitable for sperm, seek to elucidate the role of particular components of seminal fluid. The ATCC catalog teaches the composition of a particular media "designed for clonal isolation and growth" and does not mention sperm, which do not

clonally expand. U.S. Patent No. 6,150,163 similarly does not mention sperm cells and instead describes a medium suitable for chondrocyte differentiation. Of the cited references, only U.S. Patent No. 6,140,121 addresses storage of sperm in cell culture media, but does not remotely teach or suggest the present media compositions.

For these reasons, it is again respectfully requested that the rejection of the claims as obvious over Naz et al. and Lackey et al. in view of the ATCC catalogue, U.S. Patent No. 6,140,121, U.S. Patent No. 6,150,163 and Nocera et al. be withdrawn.

CONCLUSION

In view of the foregoing, reconsideration and allowance of claims 1-9, 11-13, 15, 17, 18, 23-32, 48, 49 and 54-61 is respectfully requested. The Examiner is strongly encouraged to contact the undersigned by telephone at the Examiner's convenience should any issues remain with respect to the Application.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Group Art Unit 1632

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I, Julie Mallder, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of my signature.

Julie Mallder
Signature

July 23, 2004
Date of Signature

In re

Patent Application of

Kevin J. Rozeboom, et al.

Application No. 10/081,097

Confirmation No. 2833

Filed: February 21, 2002

Examiner: Vera Afremova

"COMPOSITIONS COMPRISING REPRODUCTIVE CELL MEDIA AND METHODS FOR USING SUCH COMPOSITIONS"

DECLARATION OF DR. KEVIN J. ROZEBOOM UNDER 37 C.F.R. 1.132

I, Kevin J. Rozeboom, M.S., Ph.D., declare as follows:

1. I have personal knowledge of the following facts and I make this declaration in support of the prosecution of U.S. Patent Application Serial No. 10/081,097 before the United States Patent and Trademark Office.

2. I am currently employed as a Reproductive Physiologist and Vice President of Biotechnology Product Development at Minitube of America, Inc., a position I have held for approximately 6 months. Prior to my current position, I was employed as Director of Reproductive Technologies since May 2001.

3. My curriculum vitae is attached as Appendix A.

4. I am a co-inventor of the subject matter of the above-identified application and I am familiar with the art and with the prosecution history of this application.

5. I have reviewed the pending Office action and the cited references. In particular, I have noted that throughout the Office Action, the Examiner asserts that the claim term "medium" encompasses seminal plasma, semen samples and semen ejaculates, and bases the prior art rejections largely on this erroneous interpretation.

6. Contrary to the Examiner's assertion, seminal plasma and/or ejaculate is not considered to be a "medium," either in the context of the current application, or in the art. The terms are not understood to be synonymous or mutually inclusive.

7. The term "medium" is clearly defined in the specification as "any medium used for the collection, holding, processing, in vitro fertilization, sexing, culturing, or storing (including long-term cryopreservation) of mammalian, avian, or piscian reproductive cells, and includes both solid and liquid compositions, as well as solid compositions that are reconsistituted or mixed with a liquid carrier, such as water, for use." This definition clearly excludes seminal plasma, which would not be appropriate for any of the claimed media functions and would in no circumstances include "both solid and liquid compositions."

8. Moreover, as the context of the specification makes clear, the term "medium" is understood in the art to refer to artificial compositions, i.e., those that are prepared from individual components by the skilled artisan. For example, see paragraphs 26-29 of the specification, describing media preparation. Obviously, body fluids are not prepared by one of skill in the art in this manner.

9. The addition of the further clarifying terms regarding the medium in claim 1 further serves to make this distinction clear. As noted above, none of the claimed functions or forms of media would suitably be served by seminal plasma or semen. In fact, it has been shown that outside the body, various seminal components actually detrimentally affect sperm viability and function. For example, seminal plasma is rountinely removed prior to cryopreservation. This further underscores the fact that the claimed medium functions are not served by seminal fluid and is an additional reason that those skilled in the art do not consider seminal fluid to be a medium in any sense of the word.

10. I hereby declare that all statements made herein of my own knowledge are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated this 23 day of July, 2004.

Kevin Rozeboom

Dr. Kevin J. Rozeboom